Intact parAthyroid Hormone Assay

Ortho Clinical Diagnostics announces U.S. Food and Drug Administration (FDA) 510(k) clearance of the VITROS® intact Parathyroid Hormone (iPTH) Assay. The VITROS® iPTH Assay measures intact parathyroid hormone levels and utilizes one protocol for both routine and intraoperative testing with results available in 18 minutes. The VITROS® iPTH Assay is designed to be run in a fully automated, random access format on the VITROS® ECi/ECiQ and 3600 Immunodiagnostic Systems, and can also be run on the VITROS® 5600 Integrated System to combine clinical chemistry, routine and infectious disease immunoassay testing on a single platform. Equivalent analytical results are generated across all three systems.

Measuring intact parathyroid hormone levels aids in the differential diagnosis of hyperparathyroidism, hypoparathyroidism or hypercalcemia of malignancy. Hyperparathyroidism is excess production of calcium resulting from overactivity in the parathyroid glands.[i] Complications of hyperparathyroidism are primarily related to the long-term effect of calcium imbalances in a patient's bones and bloodstream, and may be associated with a number of health conditions, such as cardiovascular disease, kidney stones and osteoporosis.[ii]

Ortho Clinical Diagnostics has a broad, world-class menu of assays offering all of the most important clinical chemistry tests that cover major disease states including cardiology, oncology, endocrinology, infectious disease, thyroid, metabolic conditions and anemia. The VITROS® assay menu covers up to 90 percent of the top 100 assays and 99 percent of laboratory test volume, with numerous other assays in development.[iii] In addition, standardized VITROS® reagents will enable laboratories to better manage inventories and costs in addition to producing consistent test results from platform-to-platform. This is particularly beneficial for laboratories with multiple VITROS® platforms in their facilities.

VITROS® 3600 Immunodiagnostic System
The VITROS® 3600 Immunodiagnostic System is a high-capacity immunoassay system with Intelligent Sample Management for routine and specialty testing. The VITROS® 3600 Immunodiagnostic System offers a broad menu of immunoassays

worldwide, covering disease states such as cardiology, oncology, endocrinology, infectious disease, thyroid, metabolic conditions and anemia.

VITROS® 5600 Integrated System
The VITROS® 5600 Integrated System is a high-capacity system that integrates clinical chemistry and immunoassay testing on one platform using innovative Sample Centered Processing. The VITROS® 5600 platform is smaller than many other systems and does not have any water or drainage requirements, making the most of limited lab space while allowing flexibility in instrument location.

VITROS® ECi/ECiQ Immunodiagnostic System
The VITROS® ECi/ECiQ Immunodiagnostic System is a high-capacity immunoassay system with Intelligent Sample Management for routine and specialty testing designed for low- to mid-volume laboratories that require continuous processing. The VITROS® ECi/ECiQ Immunodiagnostic System offers a broad menu of immunoassays worldwide, covering disease states such as cardiology, oncology, endocrinology, infectious disease, thyroid, metabolic conditions and anemia.

For more information, visit www.orthoclinical.com [1].

[i] MayoClinic.com, Hyperparathyroidism Definition. Available at: http://www.mayoclinic.com/health/hyperparathyroidism/DS00396. Accessed July 15, 2010.

[ii] MayoClinic.com, Hyperparathyroidism Complications. Available at: http://www.mayoclinic.com/health/hyperparathyroidism/DS00396/DSECTION=complications. Accessed July 15, 2010.

[iii] OCD Data on File

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Links:
[1] http://www.orthoclinical.com